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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/587,054 | 11/22/2006 | James Pearson | 2221.008B | 4648 |
| 23405 | 7590 | 03/04/2011 | EXAMINER | |
| HESLIN ROTHENBERG FARLEY & MESITI PC | | | DESAI, RITA J | |
| 5 COLUMBIA CIRCLE | | | | |
| ALBANY, NY 12203 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/04/2011 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/587,054 | PEARSON ET AL. |
| | Examiner | Art Unit |
| | Rita J. Desai | 1625 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 January 2011.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 3-11, 14-16 and 18-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 3-11, 14-16 and 18-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 3-11, 14-16, 18-21 are under examination

Claims 24-30 are withdrawn.

Response to the arguments:-

Applicants argue that Garvey teaches compounds which stimulates endogenous production of NO. Applicants claims are drawn to cromolyn mast cell stabilizer which inhibit endogenous production of NO is found to be convincing and this rejection under 103 over Garvey has been withdrawn.

New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11, 14-16, 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite that the groups are given as residues of the parent groups but these groups do not have any indication as to where they are attached.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

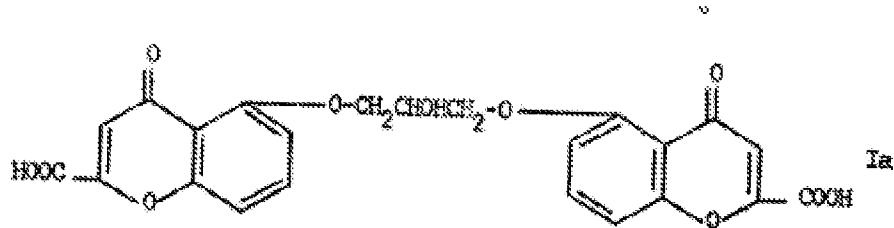
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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-8, 10, 11, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by John King et al GB 1297264.

See page 3 formula Ia .

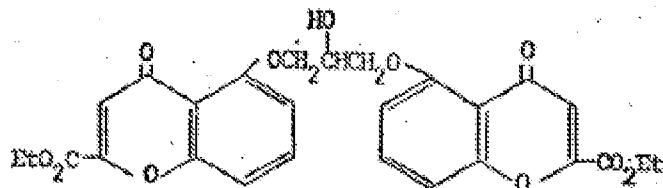


It reads on the compounds of the invention when R3 is H, and R1 and R2 are both OH.

These compounds are also used to treat asthma. See lines 52-54 page 3.

Claims 3-8, 10, 11, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by 2326227 Edward Neil Wall et al .

See page 8 formula Ib of the reference.



The compound reads on the applicants compounds when R1 and R2 are alkoxy groups.

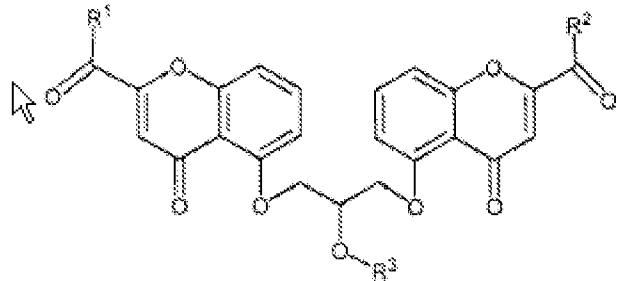
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-11, 14-16, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over John King et al GB 1297264. Johnson et al 3790580, WO 9837079, US 6355689, US 5863931 and NO synthase inhibition reduces muscle inflammation , Pizza et al. , also see Patrick Vallance reference, 1998

Applicants claims are drawn to mast cell stabilizer with many different substituents.



wherein R3 R1 R2 are groups that are

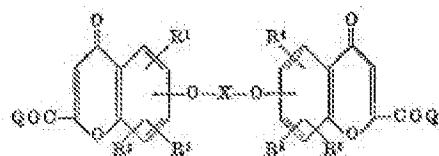
known in the prior art as admitted by the applicants in their specifications on pages 11-12.

Scope & Content of Prior Art MPEP 2141.01

Johnson et al 3790580 teaches the same mast cell

Johnson also cited in the action page 5 (and in the IDS) teaches the amine substituted groups, This formula is an intermediate.

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in which

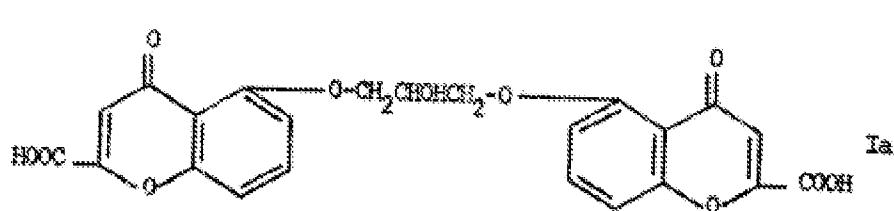
R¹, R², R³, R⁴ and R⁵ are the same or different and each represent hydrogen, halogen, hydroxy, alkyl or alkoxy, or substituted alkyl or alkoxy,

X is an optionally substituted, straight or branched hydrocarbon chain which may be interrupted by a carbocyclic or heterocyclic ring, or one or more oxygen atoms or carbonyl groups, and

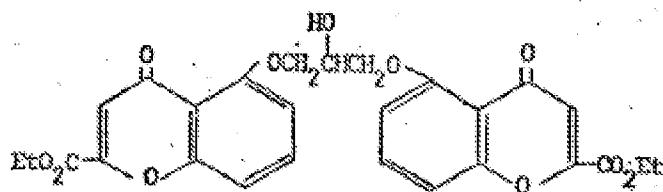
COOQ is a basic amide or a basic ester group.

John King et al GB 1297264, and Ed Neil both teach the same compounds for the same use.

King's reference see page 3 formula Ia .

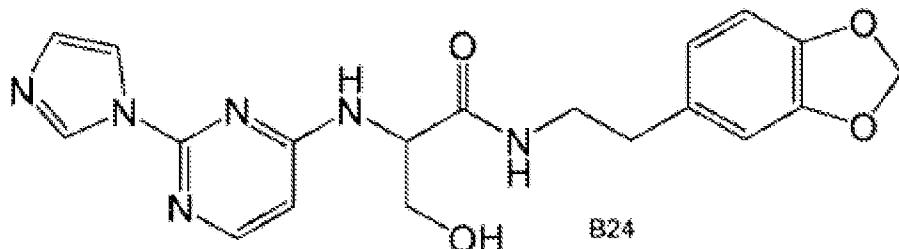


Edward Neil Wall see page 8 formula Ib of the reference.



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Applicants have admitted in the specifications , that WO 9837079 ex 53,



US 6355689, US 5863931 teach the substituents such as B24, for -OR7, or parent of R4COOH, R6NH2 and such.

And these groups are known to be inhibitors of NO .

See US 6355689.

STRUCTURE, TO PHARMACEUTICAL COMPOSITIONS CONTAINING THEM, AND TO THEIR USE IN THERAPY, IN PARTICULAR THEIR USE AS SELECTIVE INHIBITORS OF INDUCIBLE NITRIC OXIDE SYNTHASE.

Pizza et al teaches that inhibiting NO synthase reduces inflammation. Asthma is caused by inflammation.

Patrick Vallance , student BMJ 1998 also teaches the use of nitric oxide inhibition in treating asthma.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

Pizza teaches that reducing NO synthase would reduce inflammation and inherently disorders such as asthma. As does Patrick Vallance.

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John King teaches the mast cell stabilizer compound which are used to treat asthma, Various different types of NO inhibitors are known.

The use of mast cell stabilizer with different substituents such as a basic amine or basic ester groups are known to treat asthma. One of skill in the art would be motivated to insert the other known NO inhibitor groups to make compounds that are inhibitors of NO and hence treat asthma..

Conclusion

Claims 3-11, 14-16, 18-21 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

March 2, 2011.